

FACT SHEET FOR HEALTHCARE PROVIDERS: INTERPRETING SWINE INFLUENZA RT-PCR DETECTION PANEL TEST RESULTS

April 26, 2009

A public health emergency has been declared by the Secretary of Health and Human Services because of the 2009 outbreak of swine influenza A (H1N1), or “swine flu.” The Food and Drug Administration (FDA) has authorized the emergency use of the Swine Influenza RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) to test for the presumptive presence of swine influenza virus in clinical specimens under an Emergency Use Authorization (EUA). This authorization will terminate on April 26, 2010 or when the emergency has ceased to exist, whichever is earlier. The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of the rRT-PCR Swine Flu Panel.

At this time, no FDA-approved/cleared tests that identify existence of swine influenza virus in clinical specimens are available in the United States. Therefore, the Centers for Disease Control and Prevention (CDC) has developed this test to detect swine influenza virus infections. Current information on swine influenza, including case definitions and infection control guidelines, is available at <http://www.cdc.gov/swineflu/>. All information and guidelines, including those on swine influenza virus laboratory testing, may change as we continue to learn more about this disease. Please check CDC’s swine influenza virus website regularly for the most current information.

The rRT-PCR Swine Flu Panel test should be ordered to presumptively diagnose swine influenza A (H1N1) virus infection only. Nasopharyngeal or nasal swabs may be collected in the usual fashion and sent to a qualified laboratory for analysis. Specimen collection should be conducted per the clinical protocol and according to the manufacturer’s instructions for the specimen collection device.

What does it mean if the specimen tests positive for swine influenza virus?

A positive test result from the rRT-PCR Swine Flu Panel indicates that the patient is presumptively infected with swine influenza virus. The test does not indicate the stage of infection. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis. For guidelines on managing patients please refer to “*Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection in a Healthcare Setting*” and “*Interim Guidance on Antiviral Recommendations for Patients with Confirmed or Suspected Swine Influenza A (H1N1) Virus Infection and Close Contacts*” at <http://www.cdc.gov/swineflu/investigation.htm>.

The test has been designed to minimize the likelihood of false positive test results. However, should false positive results occur, risks to patients could include a recommendation for quarantine of household or other close contacts, a recommendation for patient isolation that might limit contact with family or friends, the ability to work, or the ability to receive certain medical care, prescription of an antiviral drug or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for swine influenza virus?

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative RT-PCR test should not be interpreted as demonstrating that the patient does not have swine influenza virus infection, if other aspects of the patient’s clinical presentation or recent epidemiologic exposures indicate swine influenza virus infection is likely, and diagnostic tests for other causes of acute respiratory illness are negative.

Contact Information for the Manufacturer:

CDC Influenza Division
1600 Clifton Road, MS-G03
Atlanta GA 30333
Contact phone 404-6390954

*Any significant new findings observed during the course of the emergency use of Swine Influenza RT-PCR assay will be made available at <http://www.cdc.gov/swineflu/>.